Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RABIH O. DAROUICHE

Appeal No. 2001-0599
Application No. 08/555,198

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 23-27, 30, and 35-41, all of the claims remaining. Claim 23 is representative and reads as follows:

> 23. An implantable medical device comprising:
>
> a medical device having one or more surfaces; and
>
> an antiseptic composition layer coating said one or more surfaces of the medical device, the antiseptic composition including a combination of antiseptics in an effective concentration to inhibit the growth of bacterial and fungal organisms.

The examiner relies on the following references:

Kitrilakis et al. (Kitrilakis)	3,699,956	Oct. 24, 1972
Sakamoto et al. (Sakamoto)	4,539,234	Sep. 03, 1985
Lee	4,723,950	Feb. 09, 1988
Goldberg et al. (Goldberg)	5,100,689	Mar. 31, 1992
Dangman et al. (Dangman)	5,335,373	Aug. 09, 1994

Claims 23-26, 30, and 35-37 stand rejected under 35 U.S.C. § 102(b) as anticipated by Sakamoto.

Claims 23-26, 30, 35, and 36 stand rejected under 35 U.S.C. § 102(b) as anticipated by Lee.

Claims 23-27, 30, and 35-41 stand rejected under 35 U.S.C. § 103 as obvious in view of Kitrilakis, Dangman, and Goldberg.

We affirm in part and reverse in part.

Background

The specification discloses that implanted medical devices are a common source of bacterial and fungal infections, and that various methods have been tried to prevent such infections, including coating the implanted devices with antibiotics. See pages 3-5. "However, although antibiotic-coated medical devices, such as those coated with minocycline and rifampicin, are very effective against Staphylococci, their efficacy against gram-negative bacteria and [C]andida is limited." Id., page 5.

The specification discloses that coating medical devices with antiseptics, rather than antibiotics, provides broader protection against infectious agents. The coated medical device may be, e.g., a urinary catheter or vascular catheter.

See page 6. The specification states that "'antiseptics' as used in the present invention means any of a category of antimicrobial substances that inhibits the action of microorganisms, including but not limited to chlorhexidine, methylisothiazolone, thymol, α-terpineol, cetylpyridinium chloride, and chloroxylenol." Page 8.

Discussion

The examiner rejected some of the claims as anticipated by either Sakamoto or Lee, and rejected all of the claims as obvious in view of Kitrilakis, Dangman and Goldberg. Appellants have stated that all of the claims subject to each rejection stand or fall together. Appeal Brief, page 5. Since claim 23 is the broadest claim subject to each rejection, all of the claims in each rejection stand or fall with claim 23. Claim 23 is directed to an implantable medical device which is coated on one or more surface(s) with a combination of antiseptics in a concentration effective to inhibit growth of bacteria and fungi.

1. Anticipation

The examiner rejected claims 23-26, 30, and 35-37 under 35 U.S.C. § 102(b) as anticipated by Sakamoto. Sakamoto discloses a

> urethral catheter capable of preventing urinary tract infection which [is] . . . comprised of a material selected from the group consisting of an olefin polymer, a diene polymer or a silicone polymer as the base material, and an antimicrobial substance being chemically bonded with the inside and/or outside walls of the urethral catheter.

Column 3, lines 14-24. Sakamoto states that "antimicrobial substance . . . means antibiotics, antiseptics and disinfectants." Column 3, lines 59-61. Sakamoto provides a list of exemplary antibiotics, and states that "[a]s the antiseptics and

disinfectants, it is preferred to use dyestuff medical preparations such as acrinol or acriflavine, etc., furan medical preparations such as nitrofurzone, etc., cationic soap medical preparations such as benzalkonium chloride or benzethonium chloride, etc., cyclohexidine and povidone-iodine." Column 4, lines 60-66. Finally, Sakamoto teaches that "[t]hese antimicrobial substances can be used alone or as a combination of two or more of them." Column 4, lines 67-68.

"It is well settled that a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." Celeritas Techs. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998). "[T]he description of a single embodiment of broadly described subject matter constitutes a description of the invention for anticipation purposes." In re Lukach, 442 F.2d 967, 970, 169 USPQ 795, 797 (CCPA 1971).

Sakamoto discloses a urethral catheter (an implantable medical device), having inside and outside walls (i.e., surfaces) to which are bonded antimicrobial substances, including antiseptics, which can be used in combinations of two or more. Thus, Sakamoto identically discloses all of the limitations of the instant claims. We agree with the examiner that Sakamoto anticipates instant claim 23.

Appellant does not dispute that Sakamoto discloses a urethral catheter coated with a combination of antiseptics. Rather, Appellant argues that Sakamoto's invention is limited to urethral catheters because of its "requirement for an ionic bonding step that limits the base materials to olefin polymers, diene polymers or silicone polymers." Appeal Brief, page 7. In contrast, Appellant argues, the instantly claimed invention can be applied to a wider variety of base

materials and is therefore applicable to a wider variety of implantable medical devices. Id. Appellant concludes that "the requirement for ionic bonding is a key structural difference between Sakamoto et al. and the current invention. This is all that is required to negate a § 102(b) reference." Id.

This argument is not persuasive. Whether the prior art disclosure is more limited than the instant claims does not make the claims patentable over the prior art. "It is well settled that a generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960). The instantly claimed invention—that is, the invention defined by the claims—does not exclude products coated with antiseptics bound via ionic bonding. Therefore, the claims contain no limitation that distinguishes them from prior art. The claims read on, and are anticipated by, the antiseptic-coated urethral catheters disclosed by Sakamoto. See Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983) ("The law of anticipation does not require that the reference 'teach' what the subject [application] teaches. Assuming that a reference is properly 'prior art,' it is only necessary that the claims under attack . . . 'read on' something disclosed in the reference, i.e., all limitations of the claim are found in the reference.").

The examiner also rejected claims 23-26, 30, 35, and 36 under 35 U.S.C. § 102(b) as anticipated by Lee. Since we have concluded that all of these claims are anticipated by Sakamoto, we have no need to address whether these claims are also anticipated by Lee.

2. Obviousness

The examiner rejected claims 23-27, 30, and 35-41 under 35 U.S.C. § 103 as obvious in view of the combined teachings of Kitrilakis, Dangman, and Goldberg. The examiner characterized Kitrilakis as "rais[ing] the problems of indwelling catheters, but disclos[ing] little in terms of inhibition of bacterial infection absent a steady supply of antibacterial agent, as opposed to incorporation into the catheter itself." Examiner's Answer, page 5.[1] The examiner found the deficiencies of Kitrilakis to be remedied by Dangman and Goldberg who, "also addressing the problems of medical devices in contact with bacterial sources of infection, are shown to have presented the means to simplify such bacterial inhibition; incorporation of an antibacterial coating composition with the device itself." Id. The examiner concluded that

> it would be obvious to one of ordinary skill in the art of medical devices at the time the invention was made to use one of Kitri[lak]is, modified with the further developments in order to optimize ease of use and antiseptic character Dangman and to provide acceptable protection and duration of effect, minimization of tissue damage as GOLDBERG teaches. . . . One having ordinary skill in the art would be motivated to perform these modifications in order to provide less bulky means of infection control when utilizing medical devices.

Id., page 6.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the

[1] The examiner also characterized Kitrilakis as "show[ing] the instantly claimed implanted long term urinary devices and peritoneal dialysis catheters . . . coated with an antibacterial

applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Prima facie obviousness requires, among other things, evidence of "a reason, suggestion, or motivation to lead an inventor to combine [the cited] references." Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000) (quoting In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998)).

We agree with Appellant that the examiner has not made out a prima facie case of obviousness. We find ourselves in agreement with the following argument succinctly stated in the Appeal Brief:

> The prior art cited by Examiner consists of: (1) an antimicrobial "coating" that is in reality a diffusion layer covering porous cloth or fibrous mat soaked with antimicrobials; (2) a multi-ply glove with suspended liquid antimicrobials between the plies; and (3) a method for treating surfaces to make them hydrophilic. These references do not show the "antiseptic composition layer" that is the crux of the present invention. Nor can the cited references be combined to teach the present invention. Kitrilakis et al. and Dangmann [sic] et al. are inapposite in that one slowly dispenses antimicrobial agents through a diffusion layer while the other contains its antimicrobial agents between impenetrable plies of a glove until a ply is punctured. Applying the hydrophilic surface treatment taught by Goldberg et al. to the "coating" taught by Kitrilakis et al. would result in a nonfunctional device. Combining

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composition." Examiner's Answer, page 5. For the reasons discussed infra, we consider this characterization to overstate the relevance of Kitrilakis to the instant claims.

> Goldberg et al. and Dangmann [sic] et al. would likely yield a functional glove but would certainly not teach the present invention. In short, the cited references do not render the present invention obvious.

Appeal Brief, pages 9-10. In a nutshell, the references cited by the examiner do not disclose or suggest all the limitations of the instant claims, nor do they provide a motivation to combine those limitations that are disclosed. The references therefore do not support a prima facie case of obviousness.

Summary

We affirm the rejection under 35 U.S.C. § 102(b) based on Sakamoto because the prior art reference discloses all of the limitations of the claimed invention. However, we reverse the rejection under 35 U.S.C. § 103 because the examiner has not shown that the cited references would have suggested the claimed invention to a person of ordinary skill in the art. Thus, claims 27 and 38-41 are free of any pending rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 103.

AFFIRMED IN PART

Sherman D. Winters Administrative Patent Judge	))))) BOARD OF PATENT
William F. Smith Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
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